AMENDMENT TRANSMITTAL LETTER

Docket No. 62069DIV2(51590)

Application No.	Filing Date	Examiner	Art Unit
10/823,365-Conf. #4859	April 13, 2004	G. W. Mitchell	1617

Applicant(s): Gavril W. Pasternak et al.

Invention: TOPICAL ANESTHETIC/OPIOID FORMULATIONS AND USES THEREOF

TO THE COMMISSIONER FOR PATENTS

Transmitted herewith is an amendment in the above-identified application.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED

	Claims Remaining After Amendment	Highest Number Previously Paid	Number Extra Claims Present	Rate	
Total Claims	20	- 35 =		x	
Independent Claims	1	- 3 =		x	
Multiple Dependent Claims (check if applicable)	☐				
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Dated: May 1, 2006

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Dated: May 1, 2006 Signature: Edith Sillman (Edith Sillman)

Attorney Docket No. 51590.62069 DIV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Pasternak et al.	Confirmation No.	4859
U.S. Serial No.	10/823,365	Examiner:	Mitchell, Gregory W
Filed:	April 13, 2004	Group Art Unit:	1617
For:	TOPICAL ANESTHETIC/OPIOID FORMULATIONS AND USES THEREOF		

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Date: May 1, 2006

Edith Sillman
Edith Sillman

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDMENT UNDER 37 C.F.R. § 1.11

Sir:

This paper is submitted in response to the Office Action mailed on November 30, 2006. A Petition for a two-month Extension of Time and a Declaration of the Inventors under 37 C.F.R. § 1.132 accompanies this response.

The listing of the claims begins on page 2.

Remarks begin on page 5.

AMENDMENT

Please amend the claims without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows

1. - 10. (Cancelled)

11. (Currently Amended) A method of providing topical analgesia to a subject comprising ~~topical administration of~~ topically administering to peripheral sites in the subject a pharmaceutical composition comprising ~~at least two compounds, one effecting opioid analgesia and one effecting local anesthesia, wherein the pharmaceutical composition is administered in~~ (i) synergistically effective amounts of morphine and butamben and (ii) a physiologically acceptable topical excipient, ~~and in an amount and a duration sufficient to potentiate an antinociceptive response~~ to potentiate analgesia at the peripheral sites.

12. – 15. (Cancelled)

16. (Currently Amended) The method according to claim 11, wherein the ~~analgesic~~pharmaceutical composition contains morphine ~~is administered~~ in a dose of about 0.01% to about 25% of the composition.

17. (Currently Amended) The method according to claim 11, wherein the ~~analgesic~~pharmaceutical composition contains morphine ~~is administered~~ in a dose of about 0.1% to about 10% of the composition.

18. (Currently Amended) The method according to claim 11, wherein the ~~analgesic~~pharmaceutical composition contains morphine ~~is administered~~ in a dose of about 0.5% to about 5% of the composition.

19. (Currently Amended) The method according to claim 11, wherein the ~~analgesic~~pharmaceutical composition contains morphine ~~is administered~~ in a dose of about 0.01% to about 1% of the composition.

20. (Currently Amended) The method according to claim 11, wherein the ~~analgesic~~pharmaceutical composition contains morphine ~~is administered~~ in a dose of about 0.01% to about 0.05% of the composition.

21. (Cancelled)

22. (Currently Amended) The method according to claim 11, wherein the ~~local anesthetic~~pharmaceutical composition contains butamben ~~is administered~~ in a dose of about 0.01% to about 25% of the composition.

23. (Currently Amended) The method according to claim 11, wherein the ~~local anesthetic~~pharmaceutical composition contains butamben ~~is administered~~ in a dose of about 0.1% to about 15% of the composition.

24. (Currently Amended) The method according to claim 11, wherein the ~~local anesthetic~~pharmaceutical composition contains butamben ~~is administered~~ in a dose of about 0.5% to about 5% of the composition.

25. (Currently Amended) The method according to claim 11, wherein the ~~local anesthetic~~pharmaceutical composition contains butamben ~~is administered~~ in a dose of about 0.01% to about 1% of the composition.

26. (Currently Amended) The method according to claim 11, wherein the ~~local anesthetic~~pharmaceutical composition contains butamben ~~is administered~~ in a dose of about 0.01% to about 0.05% of the composition.

27. (Original) The method according to claim 11, wherein the pharmaceutical composition further comprises a tolerance attenuating or preventing NMDA receptor antagonist and wherein the NMDA receptor antagonist is selected from the group consisting of dextromethorphan, dextrorphan, ketamine, pyroloquinoline quinone, cis-4-(phosphonomethyl)-2-piperdine carboxylic acid, MK801, memantine, and their mixtures and pharmaceutically acceptable salts thereof.

28. (Currently Amended) The method according to claim ~~11~~27, wherein the pharmaceutical composition contains the NMDA receptor antagonist ~~is administered~~ in a dose of about 0.01% to about 25% of the composition.

29. (Currently Amended) The method according to claim ~~11~~27, wherein the pharmaceutical composition contains the NMDA receptor antagonist ~~is administered~~ in a dose of about 0.1% to about 15% of the composition.

30. (Currently Amended) The method according to claim ~~11~~27, wherein the pharmaceutical composition contains the NMDA receptor antagonist ~~is administered~~ in a dose of about 0.5% to about 5% of the composition.

31. (Currently Amended) The method according to claim ~~11~~27, wherein the pharmaceutical composition contains the NMDA receptor antagonist ~~is administered~~ in a dose of about 0.01% to about 1% of the composition.

32. (Currently Amended) The method according to claim ~~11~~27, wherein the pharmaceutical composition contains the NMDA receptor antagonist ~~is administered~~ in a dose of about 0.01% to about 0.05% of the composition.

33. (Currently Amended) The method according to claim 11, wherein topical administration of the pharmaceutical composition is ~~directed~~provided to cutaneous, mucosal, vaginal, rectal, ocular, or nasal surfaces.

34. (Original) The method according to claim 11, wherein the pharmaceutical composition is topically administered to a subject in an amount and duration sufficient to prevent or relieve acute and chronic peripheral neuropathy.

35. (Original) The method according to claim 11, wherein the pharmaceutical composition is topically administered to a subject in an amount and duration sufficient to prevent or relieve neuropathic inflammation.